IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

KAREN S. BELLIAN 2873 Laurel Woods Blvd. Stow, OH 44224 and ANDREW BELLIAN 2873 Laurel Woods Blvd. Stow, OH 44224 Plaintiffs -vs- EXACTECH, INC. 2320 NW 66th Ct. Gainesville, FL 32653 (Alachua County, FL) Serve on Agent: Corporation Service Company 3366 Riverside Drive, Suite 103 Upper Arlington, OH 43221 and EXACTECH US, INC. 2320 NW 66th Ct. Gainesville, FL 32653 (Alachua County, FL) Serve on Agent: Corporation Service Company 3366 Riverside Drive, Suite 103 Upper Arlington, OH 43221 Defendants	)	CASE NO: JUDGE: **Jury Trial Demand Endorsed Hereon**

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COMPLAINT AND JURY DEMAND

Plaintiffs, KAREN S. BELLIAN and ANDREW BELLIAN, by and through undersigned counsel, hereby submit this Complaint and Jury Demand against EXACTECH, INC. ("Exactech") and EXACTECH US, INC. ("Exactech US") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries suffered as a direct and proximate result of Defendants' designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, and/or selling the defective devices sold under the name ("Optetrak" Total Knee System and/or "Optetrak Logic" Total Knee System (hereinafter "Optetrak"). In support, Plaintiffs allege the following:

I. NATURE OF THE ACTION

1. This case involves claims of strict product liability, failure to warn, breach of express and implied warranties, fraud and negligence in the designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, and/or selling of the defective (Optetrak devices) by the Defendants directly or through their agents, apparent agents, servants, and/or employees.

2. Defendants promoted their Optetrak devices as a system with three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stress, and due to their proprietary polyethylene materials, which they claimed minimized wear and lead to increased longevity.

3. On August 30, 2021, Defendants initiated a partial recall of their Optetrak devices because these devices were packaged improperly without an additional oxygen barrier layer, which can lead to expedited wear and minimized longevity of the devices.

4. On February 7, 2022, the recall was expanded to include "all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags" that were sold since 2004.

5. On February 7, 2022, Defendants sent surgeons a letter explaining that they conducted "extensive testing" and confirmed that most of their inserts manufactured since 2004 were packaged in "out-of-specification" or "non-conforming" vacuum bags that did not contain the necessary "secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance." Due to this deficiency, Defendants conceded the following:

> **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

See, URGENT MEDICAL DEVICE CORRECTION to Exactech Knee and Ankle Surgeons, February 7, 2022, a copy of which is attached hereto as Exhibit A (Emphasis in original).

6. In June of 2016, Plaintiff, KAREN S. BELLIAN, underwent Total Knee Replacement surgery on her left knee, in which an Optetrak device was implanted.

7. In the years following the surgery, Plaintiff, KAREN S. BELLIAN, experienced pain, swelling, instability, and bone loss in both knees caused by early and accelerated polyethylene wear and/or component loosening. Ultimately, on or about July 11, 2022, Plaintiff underwent an extensive revision surgery on her left knee.

8. Recipients of the Optetrak knee implants have required painful revision surgeries well before the estimated life expectancy of the devices, and at a much higher rate than should reasonably be expected for devices of this kind.

9. Until February 7, 2022, Defendants concealed their knowledge of the Optetrak devices' unreasonably dangerous risks, including an increased risk of early failure, from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

10. Despite knowledge that the Optetrak devices were defective and resulted in premature failures and accompanying complications, Defendants continued to aggressively market and sell the Optetrak Logic device, all the while maintaining that these devices were safe and effective for use in total knee replacements and concealing the hazards posed by these defective devices.

II. PARTIES

11. At all times relevant hereto, Plaintiffs, KAREN S. BELLIAN and ANDREW BELLIAN, were residents and citizens of Summit County, Ohio.

12. Defendant, Exactech, Inc., is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653 and can be served through its registered agent (Corporation Service Company, 3366 Riverside Drive, Suite 103, Upper Arlington, OH 43221). Defendant Exactech, Inc.'s stated business purpose is to "develop, manufacture, market, distribute and sell orthopedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally" and to introduce its products, including the Optetrak device, into interstate commerce, either directly or indirectly through third parties or related entities. At all times relevant to this action, Defendant Exactech, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices in interstate commerce and throughout the State of Ohio and generated substantial revenue as a result.

13. Defendant, Exactech US, Inc., a wholly owned subsidiary of Defendant, Exactech, Inc., is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653 and can be served through its registered agent Corporation Service Company (3366 Riverside Drive, Suite 103, Upper Arlington, OH 43221). According to public filings, Defendant, Exactech US, Inc. conducts Defendant, Exactech Inc.'s, sales and distribution activities in the United States. Defendant, Exactech U.S., Inc., is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing its products, including the Optetrak Logic, into interstate commerce, either directly or indirectly through third parties or related entities. At all times relevant to this action, Defendant, Exactech US, Inc., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Logic in interstate commerce and throughout the State of Ohio and generated substantial revenue as a result.

14. Exactech US, Inc. is thus also an agent, representative and/or alter ego of Defendant Exactech, Inc. Collectively, Exactech and Exactech US, Inc. are referred to herein as "Exactech" or "Defendants."

15. At all relevant times to this action, each of the Defendants and their directors and officers acted within the scope of their authority of each Defendant and on behalf of each other. At all times relevant to this action, Defendants possessed a unity of interest between themselves and exercised control over their subsidiaries and affiliates. As such, the Defendants are each individually, as well as jointly and severally, liable to Plaintiffs for Plaintiff's injuries, losses and damages as described herein.

III. JURISDICTION AND VENUE

16. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs. Defendants have significant contacts with this District by virtue of doing substantial business within this judicial district.

17. The Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. §1367.

18. The Court maintains general personal jurisdiction over Defendants as they purposely engaged in the business of designing, developing, selecting, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, their products, including the Optetrak devices and other Exactech implants, within the State of Ohio, with a reasonable expectation that the products would be used within this judicial district.

19. The Court maintains personal jurisdiction over the parties and subject matter jurisdiction over the causes of action alleged herein because the defective device at issue was implanted within this judicial district, and the defective device was subsequently removed and replaced in this judicial district after it failed.

20. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Optetrak devices to healthcare professionals in the State of Ohio, including Plaintiff's healthcare professionals, with a

reasonable expectation that such information would be used and relied upon by healthcare professionals throughout the State of Ohio, including but not limited to:

a. false representations of duration and survival of the components lasting longer than other knee implants because of proprietary use of materials and processes to give it superior wear characteristics; and/or,

b. false claims of greater forgiveness to sub-optimal implantation conditions.

21. Defendants' derived substantial revenue and benefit from their business activities within the State of Ohio, including the promotion, sale and use of the Optetrak devices.

22. Therefore, this Court has both specific and general personal jurisdiction over all named defendants.

23. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391 because the Defendants have substantial, systematic, and continuous contacts in the State of Ohio and this judicial district; because Plaintiff, KAREN S. BELLIAN, was implanted with the defective Optetrak device and was, thereafter, injured by the defective Optetrak device in this judicial district; and because Defendants are subject to personal jurisdiction within the State of Ohio and this judicial district.

IV. FACTS COMMON TO ALL COUNTS

A. Knee Replacement Surgery and Knee Implants

24. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee

joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis.

25. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a surgical procedure intended to relieve pain, improve joint function, and replace bones, cartilage and/or tissue that have been compromised by arthritis, other diseases, or trauma. The knee replacement implants designed and cleared in the 1990s met the goals of reducing pain and restoring function with low failure rates. As TKAs became more common, particularly among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene have been developed to address the issue of wear.

26. During TKA procedures, surgeons replace the joint surfaces and damaged bone and cartilage with artificial materials, such as the Optetrak device. The femoral implant is placed into the distal femur using surgical bone cement. The tibial tray is also placed with surgical bone cement. A polyethylene insert or liner is placed between the femoral implant and tibial tray to act as a cushion between the components. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

B. Defendants' Optetrak KneeDevices

27. The first Optetrak knee device was introduced to orthopedic surgeons in the United States in 1994.

28. Since 1994, Defendants have obtained 510(k) clearance from the United States Food and Drug Administration ("FDA") for various versions of Optetrak devices and tibial inserts, including the Optetrak PS, Optetrak Hi-Flex PS, Optetrak Finned Tibial Tray, Optetrak Offset Tibial Tray, Optetrak RBK Tibial Insert, Optetrak RBK Tibial Tray, Optetrak CR Slope, and Optetrak Logic.

29. At all times material hereto, Defendants designed, developed, tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Optetrak devices throughout the United States.

30. The Optetrak devices are classified as knee joint patellofemorotibial cemented prostheses. They feature a mix of polyethylene and metal-based components.

31. The Optetrak devices are comprised of the following parts: a patellar cap, femoral cap, tibial insert and tibial tray.

32. The patellar cap and tibial insert are made of polyethylene.

33. Defendants touted the Optetrak system as being first-in-class in their product brochures.

34. However, upon information and belief, by 2007 at the latest, the Defendants began receiving numerous reports regarding extremely high failure rates of the Optetrak devices, which required patients to undergo premature knee revisions.

35. Between 2007-2008, the Defendants performed an internal investigation through which they determined that the Optetrak devices had material design flaws based on verified reports from surgeons using the devices. The internal investigation further determined that there were engineering and design process failures that the Defendants attributed to the device failures.

36. Around 2008, the Defendants determined that the Optetrak Total Knee System posed a safety risk to patients due to various defects in the implant, including substantial problems with the Optetrak Tibia "Finned" Tray.

37. Beginning in 2011, the Exactech Defendants began silently replacing the "finned" tibia tray with a "fit" tibia tray and change of the polyethylene insert.

38. In studies published in 2012 and 2016, the Optetrak total knee system performed poorly when compared to its competitors.[1] The Australian Registry, a preeminent, internationally recognized orthopedic implant registry, identified the Optetrak as an implant with a higher-than-expected rate of revision..

39. Defendants promoted their Optetrak devices as having nearly three decades of clinical success and proven outcomes for patients around the world owing to an improved articular design resulting in low polyethylene stresses.

40. At all relevant times, Defendants were aware of the high rate of early failures of Optetrak devices that required patients to undergo painful revision surgeries to remove the defective device and replace it with another product.

41. Despite having actual knowledge of the increased risk of failure related to the defective nature of the Optetrak devices, Defendants made the decision not to recall, stop selling,

[1] See Thelu, C. et al., Orthopedics and Traumatology 2012; 98:413-420; see also Australian Orthopaedic Association, National Joint Replacement Registry, Hip Knee & Shoulder Arthroplasty, 2016 Annual Report.

or otherwise change the warnings for the affected devices until there was a suitable replacement approved for the U.S. market.

42. Despite Defendants' knowledge of the high rate of early onset failures of the Optetrak devices, Defendants continued to manufacture, package, promote, and distribute the Optetrak devices without alerting surgeons of the potential increased risks of early onset failures of the device.

43. Despite Defendants' knowledge of the high rate of early onset failures of the Opetrak devices, Defendants continued to manufacture, package, promote, and distribute the Opetrak devices without changing, modifying, or improving the devices or their packaging to address the increased of early failure.

44. Despite Defendants' knowledge of the high rate of early onset failures of the Opetrak devices, Defendants did not change the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks, longevity, and alternative product options with lower risks and lower rates of early failure

45. Despite Defendants' knowledge of the high rate of early onset failures of the Optetrak devices, Defendants did not even partially alert the FDA of the known increased risks until August 30, 2021, and did not more fully alert the FDA until February 7, 2022.

46. At all times relevant to this action, Defendants were aware of the problems with the Optetrak devices' design and their propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients. Nonetheless, Defendants failed to adequately warn patients, the medical community, or the public about these

risks, and continued and continued to promote, market, sell and defend the Optetrak devices without limitation until February 7, 2022.

47. On February 7, 2022, Defendants issued a Recall of their knee and ankle implants, sending an "URGENT MEDICAL DEVICE CORRECTION" Notice to "Exactech Knee and Ankle Surgeons, Hospitals, [and] Health Care Professionals" to alert them to the defects in their knee and ankle arthroplasty polyethylene inserts. The Notice explained that all three generations of Exactech knee systems had polyethylene inserts packaged in "non-conforming bags", stating specifically:

> **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

48. The Notice also acknowledged that the Optetrak devices demonstrated statistically significant higher overall revision rates compared to other knee systems in the Australian, United Kingdom, and New Zealand registries. In fact, the Notice admits that the reasons for revision potentially associated with polyethylene wear (e.g., loosening, lysis, pain) were increased three- to seven-fold in the most used Exactech Optetrak TKR combination (Optetrak-PS/Optetrak) which had a total of 263 TKR revision procedures among 2,410 primary TKRs when compared to other TKRs in the Australian Registry.

49. Defendants also prepared a sample letter for physicians to send their patients, which explains the defect in their products as follows:

> During a recent review of its knee implant manufacturing process, Exactech learned that one of the packaging layers for the plastic insert has been out of specification and may allow oxygen from the air to diffuse into the plastic insert prior to it being implanted in your knee. If a large amount of oxygen diffuses into the plastic insert while it's being stored and before it is implanted, this can lead to a process called oxidation, which can cause the plastic to wear out earlier than expected or to become damaged after it is implanted into the patient's body.
>
> See Exhibit B attached hereto.

50. The FDA classified Defendants' recall as a class II recall meaning that exposure to the product may cause temporary or medically reversible health consequences.

51. An example of a medically reversible health consequence is a revision surgery, such as the revision surgery that Plaintiff underwent on her left knee.

C. Plaintiff Specific Allegations

52. In June 2016, Plaintiff, KAREN S. BELLIAN, underwent a left TKR at Crystal Clinic, Inc. in Akron, Ohio, which is located in Summit County. The surgery was performed by Dr. Michael R. Magoline.

53. During the June 2016, procedure, a defective Optetrak device was implanted in Plaintiff's left knee cavity, including among other components, an Optetrak Logic tibial insert made of polyethylene.

54. The June 2016 arthroplasty was done correctly and did not deviate from accepted medical custom and practice with regards to the implantation of the Optetrak device.

55. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the defective implants placed inside Plaintiff, KAREN S. BELLIAN's, left knee cavity.

56. After an initial recovery period and for a period of years thereafter, Plaintiff's Optetrak devices performed as expected.

57. However, Plaintiff began to experience swelling in and around the left knee. She then began to suffer from stiffness and discomfort in the left joint, which progressed in severity. Eventually Plaintiff suffered from grinding and popping sensations, as well as significantly increased pain.

58. The pain and instability in KAREN S. BELLIAN's left knee continued to become more severe, and it became necessary to undergo a left knee revision surgery, which was performed by Dr. William F. Scully at Crystal Clinic, Inc. on July 11, 2022. Upon information and belief, Plaintiff's clinical, laboratory, and radiological workup on her left knee were negative for infection, but positive for loosening secondary to osteolysis secondary to polyethylene wear. Polyethylene wear causing osteolysis and component loosening is one the precise concerns expressed by Defendants in their communications with implanting surgeons.

59. Upon information and belief, the defective Optetrak device failed prematurely in Plaintiff's left knee.

60. Upon information and belief, the polyethylene inserts used in the Optetrak devices were defective, leading to early aseptic loosening. A packaging defect in the packaging containing the Optetrak polyethylene inserts accelerated polyethylene wear due to oxidation.

61. Upon information and belief, the defective polyethylene substance used in the Optetrak devices, and/or the defective or non-conforming packaging of said devices, caused

and/or contributed to accelerated polyethylene wear leading to early failure.

62. Upon information and belief, the defective Optetrak devices were defective in their design, manufacturing and materials at the time they left the Defendants' hands and were delivered into the stream of commerce in their defective condition.

63. It was foreseeable, expected and intended, by the Defendants that the defective Optetrak devices would be used in a knee arthroplasty patient, such as KAREN S. BELLIAN.

64. Defendants allowed the defective Optetrak device to be implanted during Plaintiff's left total knee arthroplasty in said condition.

65. Defendants failed with respect to the selection of materials, processes, testing, quality audits, and supervision of the manufacturing of their knee implant devices, including the defective Optetrak devices

66. As a direct and proximate result of the deficiencies in the defective Optetrak devices described herein, Plaintiff, KAREN S. BELLIAN, has suffered and continues to suffer injuries and damages, including without limit the following: having to undergo painful revision surgery; having required and will continue to require additional medical care and treatment, having required and will continue to require physical therapy and pain management; and having experienced and will continue to experience prolonged and lasting pain and suffering and loss of enjoyment of life.

V. CAUSES OFACTION

COUNT I
STRICT PRODUCTS LIABILITY:
MANUFACTURING DEFECT
(Pursuant to ORC §2307.71, *et seq.*)

67. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

68. Defendants had a duty to manufacture and package the Optetrak devices in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff.

69. Defendants had a duty to distribute, market, and/or sell the Optetrak devices without manufacturing defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff.

70. The defective Optetrak devices manufactured by the Defendants were not reasonably safe for their expected, intended, and/or foreseeable uses, functions and purposes.

71. The defective Optetrak devices were not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by Defendants.

72. The defective Optetrak devices were defectively manufactured and packaged for a multitude of reasons, including but not limited to the following:

a. The polyethylene substance within the defective Optetrak devices was of an inferior grade or quality than that advertised and promoted by the Defendants;

b. Defendants packaged the defective Optetrak devices in out-of-specification or non-conforming vacuum bags that did not contain secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance;

c. The polyethylene substance within the defective Optetrak devices was not made using the molding process advertised and promoted by the Defendants;

d. The polyethylene substance within the defective Optetrak devices did not comply with the required specifications for the polyethylene inserts that should be used in the devices;

e. The polyethylene inserts used in the defective Optetrak devices were not of the correct shelf age;

f. Defendants failed to perform quality control or other such testing on the polyethylene inserts used in the defective Optetrak devices to ensure they complied with required specifications;

g. Defendants failed to exercise sufficient quality control to ensure the polyethylene inserts in the defective Optetrak devices were safe for implantation in users and patients and would not degrade abnormally under average and regular use;

73. Defendants knew or should have known and been aware that the defective Optetrak devices were defectively manufactured and/or packaged.

74. The defective Optetrak devices were defective in their manufacturing, materials, and packaging at the time they left the Defendants' hands, and they were delivered into the stream of commerce in their defective condition.

75. The defective Optetrak devices should not have been distributed, marketed, and/or sold by Defendants in a defectively manufactured and/or defectively packaged condition.

76. It was foreseeable, expected and intended by the Defendants for the defective Optetrak devices to be used in a knee arthroplasty patient, such as Plaintiff.

77. The manufacturing and packaging defects of the defective Optetrak devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

78. The manufacturing and packaging defects of the defective Optetrak devices presented an unreasonable risk of harm to users and patients exposed to their danger, including

Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

79. Defendants breached their duty to manufacture and package the Optetrak devices in a manner that eliminated or prevented an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

80. Defendants breached their duty to distribute, market, and/or sell the Optetrak devices without manufacturing and packaging defects to eliminate or prevent an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

81. Plaintiff was seriously injured as a result of the manufacturing and packaging defects in the Optetrak devices caused by Defendants.

82. Defendants are strictly liable for the defective manufacture and/or defective packaging of the defective Optetrak devices; the distribution, marketing, and/or sale of the defectively manufactured Optetrak devices; and the injuries sustained by Plaintiff.

83. As a direct and proximate result of Defendants' acts and omissions, Plaintiff was implanted with the Defective Device and has suffered severe and debilitating injuries, and other damages, including but not limited to, cost of medical care, rehabilitation, permanent physical injury and damage, including instability, loss of balance, and immobility, as well as pain and suffering, for which she is entitled to in an amount to be proven at trial.

COUNT II

STRICT PRODUCTS LIABILITY: DESIGN DEFECT (Pursuant to ORC §2307.71, *et seq.*)

84. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

85. Defendants had a duty to design the defective Optetrak devices in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

86. Prior to, on, and after the dates of Plaintiff's initial knee surgeries, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

87. The Optetrak devices were defective in design and unreasonably dangerous when they entered the stream of commerce and were received by Plaintiff, because the risks were outweighed by any utility of the design of the devices and because the devices were dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Optetrak devices were in a condition not suitable for their proper and intended use.

88. The Optetrak devices were defective in design and unreasonably dangerous when they entered the stream of commerce and were received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

89. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised,

marketed, distributed, and/or sold the Optetrak devices, which were implanted in Plaintiff, such that they were dangerous, unsafe, and defective in design.

90. The Optetrak devices implanted in Plaintiff were defective in design by virtue of their size, shape, length, diameter, surface finish, molecular weight, post-consolidation treatment or lack thereof, and/or other material properties that cause the devices to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries, as well as the need for revision surgery in patients, and cause or contribute to a higher failure rate and/or shorter useful life expectancy than comparable knee replacement products.

91. The design of the packaging in which the Optetrak device components are contained is defective and not reasonably safe.

92. Plaintiff's physicians employed the Optetrak devices in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

93. The Optetrak devices as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

94. At all times herein mentioned, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices, which were implanted in Plaintiff, such that they were dangerous, unsafe, and defective. The defects in design include but are not limited to the following respects:

a. that the Optetrak has propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing

serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients;

b. that the components of the Optetrak were packaged in improperly designed vacuum bags that did not contain secondary barrier layer containing ethylene vinyl alcohol (EVOH) to prevent oxidation;

c. that the materials used within the Optetrak were of an inferior grade or quality than advertised and promoted by Defendants;

d. that the Defendants failed to conduct adequate mechanical testing, including wear or other testing, on components, subassemblies and/or the finished Optetrak;

e. that Defendants failed to test an adequate number of samples of Optetrak devices on an ongoing basis;

f. that Defendants failed to take adequate steps to specifically identify failure modes with the Optetrak with clarity and to suggest methods to monitor, avoid and/or prevent further failures;

g. that Defendants failed to take corrective actions to eliminate or minimize further failures of the Optetrak devices;

95. As alleged herein, Defendants knew and had reason to know that the Optetrak caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other premature failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need or revision surgery in patients. Defendants consciously disregarded this increased risk of harm by failing to adequately warn of the risk; unlawfully concealing the dangerous problems associated with implantation of the Optetrak; and continuing to market, promote, sell, and defend the Optetrak devices.

96. It was foreseeable, expected and intended by the Defendants for the defective Optetrak devices to be used in a knee arthroplasty patient, such as Plaintiff.

97. The design defects of the Optetrak devices presented an unreasonable risk of harm when they were used and operated for purposes expected and intended by Defendants.

98. The design defects of the Optetrak and Optetrak packaging presented an unreasonable risk of harm when they were used in a manner that was or should have been foreseeable to Defendants.

99. Pre-existing feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Optetrak devices and Optetrak packaging were designed and offered for sale in the market.

100. Defendants failed to balance the feasibility of safer alternative designs for the Optetrak and Optetrak packaging against existing risks of injury.

101. Defendants failed to use pre-existing feasible safer alternative designs providing the same functional purpose.

102. Defendants failed to use their own pre-existing feasible safer alternative designs providing the same functional purpose.

103. Defendants failed to take into account the reasonable cost of feasible safer alternative designs.

104. Defendants failed to balance the risks of injury against the utility and costs of feasible safer alternative designs.

105. Defendants failed to develop feasible safer alternative designs providing the same functional purpose with reasonable price adjustments.

106. Defendants failed to take into account improvements related to safety and injury prevention presented by feasible safer alternative designs.

107. Defendants failed to consider foreseeable safety hazards and serious injury risks arising from the Optetrak device's design.

108. Defendants breached their duty to design the Optetrak devices in a manner that eliminates or prevents an unreasonable risk of harm or injury.

109. As alleged herein, the defects in design of the Optetrak were a substantial factor in causing Plaintiff's injuries.

110. Plaintiff was seriously injured as a result of the design defects in the Optetrak devices.

111. Defendants are strictly liable for the defective design of the Optetrak; the distribution, marketing, and/or sale of the defectively designed Optetrak devices; and the injuries sustained by Plaintiff as a result thereof.

112. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT III

STRICT PRODUCTS LIABILITY: FAILURE TO WARN (Pursuant to ORC §2307.71, *et seq.*)

113. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

114. At all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised,

marketed, distributed, and/or sold the Optetrak devices for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

115. The Optetrak device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff because the risks were outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Optetrak device was in a condition not suitable for its proper and intended use.

116. The Optetrak device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or their sales force to physicians and patients with or about the Optetrak failed to adequately convey the potential risks and side effects of the Optetrak device and the dangerous propensities of the device, which risks were known or were reasonably knowable to Defendants. In particular, Defendants failed to adequately disclose the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients which risks exceeded or outweighed the purported benefits associated with the device.

117. The Optetrak device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff because the Optetrak device posed increased risks of harm and side effects that were known or knowable to Defendants by the use of available scientific knowledge.

118. Defendants knew or should have known of the defective condition, dangerous characteristics, and risks associated with the Optetrak device as alleged herein.

119. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Optetrak; and continuing to market, promote, sell and defend the Optetrak.

120. The Optetrak device that was manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

121. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered by the exercise of reasonable care, the defects mentioned herein and perceived their danger.

122. Defendants, as manufacturers and/or distributors of the Optetrak devices, are held to the level of knowledge of an expert in the field.

123. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous.

124. The Optetrak device was expected to and did reach Plaintiff and Plaintiff's healthcare providers without substantial change in its condition as manufactured, packaged, distributed, and sold by Defendants.

125. Plaintiff, individually and through Plaintiff's physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

126. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Optetrak devices.

127. Had Plaintiff received adequate warnings regarding the risks of the Optetrak device, Plaintiff would not have used it or allowed her surgeon to implant it in her body.

128. Plaintiff's healthcare providers stored, handled, and used the Optetrak device in the manner in which it was intended to be stored, handled, and used, making such use reasonably foreseeable to Defendants.

129. The lack of adequate and accurate warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or its sales force to physicians and patients with or about the Optetrak device prior to, on, and after the dates of Plaintiff's initial knee surgeries were a substantial factor in causing Plaintiff's injuries, losses and damages as alleged herein.

130. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable and, in fact, were being sold and marketed by Defendants and/or other manufacturers at the time Defendants sold the Optetrak device to Plaintiff.

131. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT IV

NEGLIGENCE
(Pursuant to ORC §2307.74, *et seq.*)

132. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force

and effect as if more fully set forth herein.

133. Defendants had a duty to exercise reasonable care in the design, manufacture, packaging, sale and/or distribution of Optetrak devices into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

134. Defendants breached their duty and failed to exercise ordinary care in the design, formulation, manufacture, packaging, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Optetrak devices into interstate commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

135. Defendants failed to exercise due care under the circumstances, and their negligence and recklessness includes the following acts and omissions:

a. Negligently manufacturing, or failing to select appropriate third-parties to produce, the polyethylene components used in the Optetrak devices;

b. Negligently packaging, or failing to select appropriate third-parties to package, the polyethylene components used in the Optetrak devices;

c. Negligently failing to properly supervise and monitor the production and packaging of the polyethylene components used in the Optetrak devices;

d. Negligently failing to properly and thoroughly select the material used in the Optetrak devices;

e. Negligently failing to properly and adequately test the Optetrak devices and their attendant parts before releasing the devices to market;

f. Negligently failing to conduct sufficient post-market testing and surveillance of the defective Optetrak devices;

g. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the defective Optetrak devices in accordance with good practices;

h. Negligently designing, manufacturing, packaging, marketing, advertising, distributing, and selling the Optetrak devices;

i. Continuing to negligently manufacture and distribute the defective Optetrak devices after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates; and

j. Negligently violating applicable state and federal laws and regulations.

136. Despite the fact that Defendants knew or should have known that the Optetrak devices posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market devices for use by consumers and/or continued to fail to comply with federal requirements.

137. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

138. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

139. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT V

NEGLIGENT MISREPRESENTATION
(Pursuant to ORC §2307.77, *et seq.*)

140. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

141. At the time Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices to Plaintiff and/or Plaintiff's healthcare providers, Defendants knew or should have known of the use for which the devices were intended and the serious risks and dangers associated with such use of the Optetrak devices.

142. Defendants owed a duty to orthopedic surgeons, other healthcare providers and to consumers of the Optetrak device, including Plaintiff, to accurately and truthfully represent the risks of the Optetrak device. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's healthcare providers, the medical community, Plaintiff, and the public about the risks of the Optetrak device, including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendants knew or in the exercise of diligence should have known.

143. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the Optetrak device was safe, had an excellent performance record, and did not have a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

Instead, and in Plaintiff's case, Defendants stated or implied to physicians, patients and the FDA that any problem with the Optetrak devices in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Optetrak device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons and the FDA

144. Despite their knowledge of serious problems with the Optetrak device, Defendants urged their sales representatives to continue marketing the Optetrak device, and distributed medical literature, white papers, non-peer reviewed studies, and other communications to physicians in an effort to mislead them and the general public about the risks associated with the Optetrak device and instead create the image and impression that the Optetrak device was safe.

145. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT VI

FRAUDULENT MISREPRESENTATION
(Pursuant to ORC §2307.77)

146. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

147. Defendants, having undertaken to test, study, research, design, formulate, manufacture, inspect, label, package, promote, advertise, market, distribute and sell the Optetrak

device, owed a duty to provide accurate and complete information to Plaintiff, her healthcare providers, and the public regarding the safety and efficacy of the Optetrak.

148. However, Defendants misled Plaintiff, Plaintiff's healthcare providers, and the public into believing that the Optetrak device was safe and effective for use in total knee replacement surgery and engaged in deceptive, misleading and unconscionable promotional, marketing and sales tactics to convince healthcare providers and patients to use the Optetrak, even though Defendants knew or should have known that the Optetrak was unreasonably dangerous as alleged herein. Defendants also failed to warn healthcare providers and the public about the serious risks associated with the use of the Optetrak including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

149. Defendants' advertising campaigns, marketing materials and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Optetrak was safe for human use and had no unacceptable risks.

150. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the Optetrak. Defendants, through sales representatives, advertisements, and other marketing and promotional practices and communications as well as through the publication of medical literature and non-peer reviewed studies, deceived healthcare providers, Plaintiff, other patients, and the public about the true risks of the Optetrak device. Defendants falsely and deceptively kept relevant information from

healthcare providers, the FDA and the public, including Plaintiff, regarding the safety of the Optetrak.

151. Defendants expressly denied that the Optetrak created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence regarding the increased likelihood of injury from the Optetrak device including but not limited to the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

152. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, healthcare providers, Plaintiff, and the public, the truth regarding Optetrak's failures for years, all the while undertaking sales, marketing and promotional campaigns to sell the Optetrak. Defendants received reports of defects in its Optetrak devices from various sources, including those alleged herein, and intentionally withheld this information from the FDA, healthcare providers, Plaintiff, and the public, while continuing to sell the Optetrak for implantation in patients such as Plaintiff.

153. Further, even as Defendants disclosed some information regarding the Optetrak device's defects, the disclosures were inadequate, incomplete, and misleading.

154. Through their wrongful conduct, Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Optetrak device. Defendants failed to fully inform healthcare providers, Plaintiff, other patients, and the public of the true risks associated with the Optetrak, which were known to Defendants, and continued to assure healthcare providers and patients that the Optetrak was safe and effective device for the

purpose of continuing to derive substantial profits from its sale.

155. Through their advertising campaigns, sales and marketing materials and promotional items, Defendants falsely and deceptively misrepresented and omitted numerous material facts regarding the Optetrak, including but not limited to the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

156. Defendants possessed evidence demonstrating the Optetrak caused serious injuries. Nevertheless, Defendants continued to market the Optetrak by providing false and misleading information about the device's safety and efficacy to Plaintiff and Plaintiff's healthcare providers.

157. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's healthcare providers, and the public were Defendants' assurances that the Optetrak was a safe device and had a low failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Optetrak in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Optetrak Device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons.

158. Despite their knowledge of the risks with the Optetrak, Defendants urged their sales representatives to continue marketing it and distributed medical literature, non-peer

reviewed studies, and other communications to healthcare providers which did not adequately convey the risks of the device in an effort to mislead them and the public about the serious risks associated with its use.

159. Defendants engaged in all the acts and omissions alleged herein with the intent that Plaintiff and Plaintiff's healthcare providers would rely on the misrepresentations, deceptions and concealments in deciding to implant and use the Optetrak rather than another of product.

160. Plaintiff and Plaintiff's healthcare providers justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations and this reliance proximately caused Plaintiff's injuries and damages as alleged herein.

161. Plaintiff's healthcare providers relied upon information obtained from Defendants, the medical literature, journal articles, medical conferences and presentations, adverse event reporting data, and discussions with other healthcare providers to get information about the performance and safety profile of medical devices including the Optetrak device. However, all these sources of information failed to include information about the true risks of the Optetrak device because these risks, which were known to Defendants, were actively concealed or misrepresented by Defendants.

162. Had Defendants disclosed accurate, complete and truthful information about the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, Plaintiff would not have allowed her physician to implant the Optetrak device into her body.

163. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT VII

FRAUDULENT CONCEALMENT

164. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

165. At all times during the course of dealing between the Defendants, Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of Optetrak devices for their intended use.

166. Defendants knew or were reckless in not knowing that their representations were false.

167. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to the fact that:

a. the subject product was not as safe as other similar devices indicated for knee arthroplasty;

b. that the subject product was defective, and that it caused dangerous side effects, including but not limited to component loosening, component mal-alignment, substantial early polyethylene wear, pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the device, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects versus other knee arthroplasty devices;

c. that the subject product was manufactured and/or packaged negligently;

d. that the subject product was manufactured and/or packaged defectively;

e. that the subject product was manufactured and/or packaged improperly;

f. that the subject product and/or product packaging was designed negligently;

g. that the subject product and/or product packaging was designed defectively; and

h. that the subject product and/or product packaging was designed improperly.

168. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries, as well as the need for revision surgery in patients.

169. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Optetrak devices, including the Plaintiff.

170. Defendants' concealment and omissions of material facts concerning, *inter alia,* the safety of Optetrak devices was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the devices, and to cause them to purchase, prescribe, dispense and/or use the subject product.

171. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

172. Plaintiff, as well as Plaintiff's physicians, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

173. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT VIII

BREACH OF EXPRESS WARRANTY

174. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

175. At all times herein mentioned, the Defendants manufactured, packaged, distributed, recommended, merchandized, advertised, promoted, and sold the Optetrak devices. These actions were under the ultimate control and supervision of Defendants.

176. Defendants expressly represented and warranted that Optetrak Devices were safe and effective devices for those patients requiring a knee replacement.

177. Optetrak devices manufactured, packaged, and sold by Defendants did not conform to these express representations and warranties because they caused serious injury to the Plaintiff when used as recommended and directed.

178. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue.

179. The Optetrak device was injected into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition, and the product's materials were expected to and did reach users, handlers, and persons encountering said products without substantial change in the condition in which they were sold.

180. Plaintiff and Plaintiff's healthcare providers relied on Defendants' express representations and warranties about the safety and efficacy of the Optetrak device.

181. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the skill and judgment of Defendant as to whether the Optetrak was of merchantable quality and safe and fit for its intended use.

182. Defendants' conduct as described herein was a proximate cause of damages to Plaintiff.

COUNT IX

BREACH OF IMPLIED WARRANTY

183. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

184. At all times herein mentioned, the Defendants manufactured, packaged, distributed, recommended, merchandized, advertised, promoted, and sold the Optetrak devices. These actions were under the ultimate control and supervision of Defendants.

185. At the time Defendants designed, manufactured, packaged, marketed, sold, and distributed the Optetrak device for use by the Plaintiff, Defendants knew of the use for which the Optetrak device was intended, impliedly warranted the product to be of the use for which the Optetrak device was intended, impliedly warranted the product to be of merchantable quality and safe for such use, and that its design, manufacture, packaging, labeling, and marketing complied with all applicable federal requirements.

186. These representations and warranties were false, misleading, and inaccurate in that the Optetrak device was unsafe, unreasonably dangerous, not of merchantable quality, and defective.

187. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue.

188. Plaintiff and Plaintiff's healthcare providers relied on Defendants' implied representations and warranties about the safety and efficacy of the Optetrak device.

189. The Plaintiff and/or Plaintiff's healthcare providers reasonably relied upon the skill and judgment of Defendants as to whether the Optetrak device was of merchantable quality and safe for its intended use, and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

190. The Defendant breached the aforesaid implied warranties, as its Optetrak device was not fit for its intended purposes and uses.

191. Contrary to Defendants' implied warranties, the Optetrak device was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

192. Defendants' conduct as described herein was a proximate cause of damages to Plaintiff.

COUNT X

VIOLATION OF OHIO CONSUMER SALES PRACTICES ACT

193. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

194. The above-named Plaintiff, KAREN BELLIAN, alleges that she is a Consumer entitled to the protections of the Consumer Sales Practices Act, Ohio Revised Code §1345.01 *et seq.* (hereinafter "O.R.C."), in that she received the Optetrak device as manufactured, marketed and supplied by Defendants.

195. Defendants supplied Plaintiff, KAREN BELLIAN's, medical provider(s) with the product, and accordingly are suppliers in connection with consumer transactions pursuant to O.R.C. §1345.01 *et seq.*

196. Defendants deceived Plaintiff in violation of O.R.C. §1345.02(A) of the Act by promoting, soliciting, effecting and/or allowing sales with the use of unfair, false, misleading or deceptive acts or practices to Plaintiff, either directly or indirectly through her medical provider(s).

197. Defendants engaged in deceptive acts and practices pursuant to O.R.C. §1345.02(B)(2) as a supplier in connection with consumer transactions in that Defendants knew at the time that the transactions were entered into that it deceptively represented that the Optetrak device was of a particular standard, quality and grade or prescription.

198. Defendants engaged in unconscionable acts and practices pursuant to O.R.C. §1345.03(B)(6).

199. Defendants knowingly accepted the benefits of its deception in the form of profits from the increased sales.

200. Defendants should have taken affirmative steps to warn consumers, such as Plaintiff, KAREN BELLIAN, and/or her prescribing physicians, of the potential harm of the Optetrak device.

201. As a direct and proximate result of Defendants' deceptive and unconscionable acts and practices, Plaintiff, KAREN BELLIAN, has suffered injuries and damages as described herein.

202. Plaintiff, KAREN BELLIAN, further alleges that Defendants knowingly committed acts and practices in violation of the Ohio Consumer Sales Practices Act and is accordingly responsible for attorneys' fees.

COUNT XI

PUNITIVE DAMAGES CLAIM

203. Plaintiff realleges and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

204. Plaintiff is entitled to an award of punitive and exemplary damages based upon the Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total disregard for the public safety and welfare.

205. The Defendants had knowledge of, and were in possession of evidence demonstrating that, the Optetrak device was defective, unreasonably dangerous, and had a substantially higher failure rate than did other similar devices on the market. Despite their knowledge, the Defendant failed to, among other purposeful acts, inform or warn Plaintiff, Plaintiff's agents, or her healthcare providers of the dangers, establish and maintain an adequate quality and post-market surveillance system, and recall the Optetrak device from the market sooner.

206. As a direct and proximate result of the Defendants' acts and omissions as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT XII

LOSS OF CONSORTIUM

207. Plaintiffs re-allege and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

208. Prior to the initial implantation of Defendants' Defective Device, and at all other times material hereto, Plaintiff, ANDREW BELLIAN, was legally married to Plaintiff, KAREN S. BELLIAN.

209. As a direct and proximate result of the acts and omissions of the Defendants, as set forth above, Plaintiff, ANDREW BELLIAN, as spouse of Plaintiff, KAREN S.

BELLIAN, has suffered consequential damages and has been deprived of his spouse's full society, care, comfort, companionship, and has otherwise suffered a loss of consortium.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a) For damages in a sum in excess of $75,000, the jurisdictional minimum of this Court for;

1) Physical pain and suffering in the past and which, in reasonable probability she will continue to suffer in the future;

2) Physical impairment and incapacity in the past and which, in reasonable probability she will continue to suffer in the future;

3) Mental anguish in the past and which, in reasonable probability, she will sustain in the future;

4) Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses she will need in the future;

5) Disfigurement in the past and which, in reasonable probability, she will continue to suffer in the future;

6) For damages under the Ohio Consumer Sales Practices Act;

7) For loss of consortium damages, and

8) Punitive damages.

b) Plaintiff be awarded full, fair and complete recovery for all claims and causes of action relevant to this action;

c) Plaintiff be awarded all appropriate costs, fees, expenses and pre-judgment and post judgment interest pursuant to the laws of the State of Ohio as authorized by law on the judgments entered in Plaintiff's behalf, and

d) Such other relief the Court deems just and proper.

Dated: _____, 2022

Respectfully submitted,

/s/ Barry M. Ward
BARRY M. WARD, 0014991
BARRY M. WARD CO., LPA
Attorney for Plaintiffs
304 N. Cleveland-Massillon Road
Akron, OH 44333
(330) 535-1555

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

/s/ Barry M. Ward
BARRY M. WARD, 0014991
BARRY M. WARD CO., LPA
Attorney for Plaintiffs